PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Matthew During
Application No:	09/491,896
Filing Date:	January 24, 2000
Entitled:	VACCINE MEDIATED TREATMENT OF NEUROLOGICAL DISORDERS
Atty. Docket No:	102194-6

Group Art Unit: 1647

Examiner: B. O'Laughlin

#8 B.O'L 12/14/00

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December 4, 2000 — Date of Signature and Mail Deposit

By: Thomas J. Engellenner
Reg. No: 28,711

RESPONSE TO RESTRICTION/ELECTION REQUIREMENT

Assistant Commissioner for Patents
Washington, DC 20231

Dear Sir:

Response to Restriction Requirement Under 35 U.S.C. §§121. In the Office Action mailed from the Patent Office on September 7, 2000, the Examiner required election of one of the following groups:

Group I: Claims 1-12, 22, 25-32, 36, 38-44, 54, 56-68, 70 and 72-74;

Group II: Claims 1-12, 22, 25-32, 36, 38-44, 54, 56-68, 70 and 72-74;

Group III: Claims 1-5, 13-24, 33-37, 45-54, 59-68;

Group IV: Claims 70-71, 75-81;

Group V: Claims 70-74; and

Group VI: Claims 82-85.

The invention is directed to methods and compositions for treating neurological disorders with compositions that contain antibodies, or with a vaccine comprising antigens that can elicit the production of antibodies in the circulatory system of a subject. One of the novel features of the invention is that the circulating antibodies are effective against targets in the central nervous system. For example, Applicant has demonstrated that antibodies generated in the circulatory system against a central nervous system target, such as the NMDR receptor, are effective in successfully treating at least two neurological disorders (*e.g.*, stroke and epilepsy), using the same antibody target, *i.e.*, the NMDR receptor. This invention clearly has a single broad unifying concept, as reflected in claim 1.

For the purpose of being responsive to the outstanding Office Action however, Applicant hereby elects the Group I invention (claims 1-12, 22, 25-32, 36, 38-44, 54, 56-68, 70 and 72-74 drawn to a method of treating a neurological disorder by administering an amino acid vaccine), with traverse.

With regard to the three-way election of species requirement, Applicant elects the species of a epilepsy (claims 3 and 5 in group I), the species of monoclonal antibodies (claim 64 in group I), and the species of neuroreceptors (claims 6, 25, 38, 68 and 72 in group I), with traverse. It is Applicant's understanding that the species election is for searching purposes only and upon a finding of allowability of the elected species, the remaining species will also be searched. Also that under 35 U.S.C. §§121, an election of a single species for prosecution on the merits is required, to which the claims will be restricted if no generic claim is finally held allowable. Applicant further understands that upon the allowance of a generic claim, they will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. §§ 1.141 et seq.

Applicant respectfully traverses the restriction requirement as improper and reconsideration and withdrawal of the restriction requirement is requested because the invention has a unifying inventive concept of using circulating antibodies that are effective against targets in the central nervous system. The antibodies are generated either by an antigen that elicits the production of the antibodies, or is a composition comprising antibodies directed to targets in the central nervous system. The separation of invention into different groups appears to be improper. A more appropriate separation is in terms of species rather than separate groups of inventions. For example, the invention of Group I and Group II are merely different embodiments of the same invention, *i.e.*, using circulating antibodies to treat a neurological disorder. According to the Examiner, the Group I claims are drawn to an amino acid vaccine while the Group II claims are drawn to a nucleic acid vaccine. Applicant disagrees with the restriction of the claims into separate groups because the underlying invention is the use of circulating antibodies to treat a neurological disorder, not how the antibodies are produced. The method of producing the antibodies are mere embodiments of the same invention.

Moreover, reconsideration and withdrawal of the species election requirement is also requested insofar as a single search should suffice to examine all of the members in a Markush groups, for example, the Markush group drawn to antibodies (Claims 15, 35, 51, 64, and 79). The requirement of a Species Election of members from a Markush group is improper "if the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they are directed to independent and distinct inventions." Furthermore, a "unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility." MPEP section 803.02.

Applicant believes that Markush claims to antibodies and antibody fragments share a common utility because they all bind to, and modify a target protein. The same modification of

the target protein can be accomplished with full length antibodies, or various fragments thereof. Applicant also believes that the members of the Markush group are so closely related that a search and examination of the entire claim would not be burdensome.

Furthermore, Applicant believes that in electing the Group I invention, Applicant has chosen to pursue claims drawn to a method of treating a neurological disorder by administering an amino acid vaccine that elicits the production of a specific antibody. As such, the Examiner's requirement of an election to a *composition* comprising a therapeutically effective amount of an isolated antibody, where a species election is required for a class of antibodies and antibody fragments, is inappropriate because the elected claims are not drawn to a composition of antibodies.

The Examiner is urged to call the undersigned at the telephone number indicated below so that any remaining issues can be discussed.

Respectfully submitted,
NUTTER, McCLENNEN & FISH, LLP

Date: December 4, 2000

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